K071078

Section 807.87 (h) A 510(k) Summary as described in Section 807.92 or a 510(k) statement as described in 807.93

MAY 2 2 2007

Premarket Notification [510(k)] Summary as required by 21 CFR 807.92

Date summary was prepared:

March 2007

Submitter's Name:

.decimal, Inc.
121 Central Park Place
Sanford, Florida 32771

Contact Person:

Daniel L. Bennett
Director of Quality and Regulatory Affairs
Phone: 407-330-3300
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Device Name:

.decimal Range Compensator

Classification Name:

IXI
21 CFR892.5710
Class II

Predicate Device(s):

.decimal, Inc. DECIMAL TISSUE COMPENSATOR / INTENSITY MODULATOR, 510k # K040804

Intended Use:

.decimal's Range Compensator manufacturing service manufactures the solid Range Compensators for intensity modulation of external beam proton radiation therapy. The Range Compensator are designed by the customer's treatment planning system to block radiation from hitting critical structures and healthy tissue while guiding the radiation to the targeted area.

Summary of Technological Characteristics:

The device features of .decimal's Apertures are similar to the predicate device .decimal Tissue Compensator and Intensity Modulator. They both are used for external beam radiation therapy treatments, they both are used to block radiation and guide it to affected areas. The target population is identical and the use parameters are also very similar.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Daniel L. Bennett
Director of Quality and Regulatory Affairs
.decimal, Inc.
121 Central Park Place
SANFORD FL 32771

MAY 22 2007

Re: K071078
Trade/Device Name: .decimal Range Compensator
Regulation Number: 21 CFR 892.5710
Regulation Name: Radiation therapy beam-shaping block
Regulatory Class: II
Product Code: IXI
Dated: April 12, 2007
Received: April 17, 2007

Dear Mr. Bennett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known) K071078

Device Name: .decimal Range Compensator

Indication for Use:

In proton therapy for cancer, a proton beam is aimed at the cancerous tissue using a large "snout". The "snout" is rotated around the patient using a large, three-story gantry. While the patient lies on a treatment table, the gantry rotates around and points the snout at pre-determined positions to maximize efficiency and dose delivery to the tumor volume. Each gantry angle, or "port", requires two custom-made, beam modifying, patient specific devices: a ***range compensator*** and an ***aperture***.

The ***range compensator*** is made out of acrylic or wax. The custom shape/design specifications for ***range compensators*** are generated out of the treatment planning system and are unique to each patient and each gantry angle (most patients will have 2-3 different gantry angles.) The outer dimensions/specifications are vendor specific, based upon the manufacturer of the proton delivery machines.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K071078